IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

ANNIE TUMMINO, *et al.*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 12-CV-763
MARGARET HAMBURG, Commissioner of Food and Drugs, *et al.*,	)	(Korman, J.) (Pohorelsky, M.J.)
Defendants.	)	

DECLARATION OF JANET WOODCOCK, M.D.

On behalf of defendants Margaret Hamburg, Commissioner of Food and Drugs, and Kathleen Sebelius, Secretary of Health and Human Services, I, Janet Woodcock, M.D, declare pursuant to 28 U.S.C. § 1746, under penalty of perjury, that the following is true and correct:

1. I am the Director of the Center for Drug Evaluation and Research ("CDER"), United States Food and Drug Administration ("FDA"), United States Department of Health and Human Services ("HHS"). I joined FDA in 1986 and since then have been the CDER Director for a total of more than 15 years. I have also held the positions of Deputy Commissioner, Chief Medical Officer, and Director of the Office of Therapeutics Research and Review in FDA's Center for Biologics Evaluation and Research. I received my medical degree from Northwestern University Medical School,

and my undergraduate degree from Bucknell University. I have held teaching appointments at Pennsylvania State University and the University of California at San Francisco.

2. In my capacity as CDER Director, I am familiar with CDER's evaluations of levonorgestrel-based contraceptive drug products, including Plan B and Plan B One-Step. This declaration is based on that familiarity, as well as on CDER's official records related to those evaluations prepared in the regular course of business. All such records were made at or near the time of the act, event, or condition described therein, by or from information transmitted by a person with knowledge of such act, event, or condition.

3. In connection with the above-captioned case, I understand that on April 5, 2013, the district court ordered FDA to "make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within thirty days." I write this declaration on behalf of FDA and HHS to provide an update to the court regarding the current approval status of Plan B One-Step and in support of the government's motion for stay of that order pending appeal.

a. With regard to the approval status of Plan B One-Step, on April 30, 2013, FDA approved an amended supplemental new drug application (SNDA) submitted by Teva Branded Pharmaceutical Products R&D, Inc. ("Teva") seeking to market Plan B One-Step with no prescription requirements for any consumer but with labeling that states that the drug is not intended for use by, or sale to, consumers under age 15. A copy of FDA's approval letter is attached. Teva submitted the amended SNDA on March 9, 2012. The application was not a matter of public

record prior to FDA's action; FDA does not generally disclose the existence of an application before approval absent permission from or disclosure by the sponsor. 21 C.F.R. § 314.430.

b. Prior to FDA's approval of the amended SNDA, Plan B One-Step was available only in a dual packaging configuration in which the prescription version and the non-prescription version were packaged in the same box. For that reason, the package could be dispensed only by a pharmacist even to customers who were not required to present a prescription. The newly approved Plan B One-Step no longer includes a prescription version for younger age groups and, therefore, no longer needs to be dispensed by a pharmacist.

c. Teva has indicated that Plan B One-Step will be distributed to retailers with an on-site pharmacy, and that it may be placed in the family planning, female health, or similar aisle. Thus, the product will be available for sale during the retailer's normal operating hours, whether the pharmacy is open or not.

d. Teva's amended SNDA that has now been approved by FDA proposed the following notice on the product label: "NOT FOR SALE TO THOSE UNDER 15 YEARS OF AGE | PROOF OF AGE REQUIRED | NOT FOR SALE WHERE AGE CANNOT BE VERIFIED." Teva plans to package its product with a UPC code that, when scanned, would prompt the cashier to request proof of age from the customer. If age verification cannot be performed, or if the customer does not meet the

age requirement for the product, the cashier would be instructed not to proceed with the sale. Teva noted its willingness to conduct an audit of the age verification practices after the product is approved to ensure that the age restriction is being enforced.

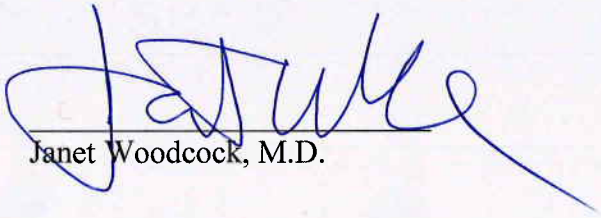
e. The amended SNDA indicated the sponsor's commitment to educate consumers, pharmacy staff, and healthcare professionals about the product's new status and about the fact that the product is not for sale to persons under age 15.

f. In connection with its approval of Teva's amended SNDA, FDA granted Teva three years of marketing exclusivity on the basis of actual use studies Teva conducted in women age 15 and 16 that FDA found essential to its approval. The approval does not affect the prescription or approval status of Plan B or its generic equivalents. The generic equivalents to Plan B remain available to those age 17 and older without a prescription and to those under age 17 with a prescription. Generic equivalents to Plan B are kept behind the pharmacy counter for the prescription product to be lawfully dispensed.

4. FDA recognizes that its approval of Teva's amended SNDA for-over-the counter sale of Plan B One-Step for ages 15 and above does not and was not intended to provide all of the relief set forth by the district court. The approval reflects FDA's judgment that the application submitted by Teva was supported by appropriate scientific data showing that Plan B One-Step could be used safely and effectively as a nonprescription product by females ages 15 and up.

5. The public properly relies upon FDA classification of drugs as non-prescription as a reflection of the agency's judgment regarding the safety and proper use of a drug without a doctor's prescription. The public interest will not be served by reclassification of drugs as non-prescription by order of a court, without appropriate agency decision-making procedures being followed. A stay of the court's order will prevent public uncertainty regarding the status of the drugs at issue here pending the government's appeal to the Second Circuit. Moreover, if the status of these drugs is changed and later reversed, it can lead to situations in which women mistakenly believe that they can obtain the drug without a prescription or at certain locations where it used to be, but is no longer, available. The problem would be exacerbated because products with incorrect labeling will presumably remain on pharmacy shelves even after an appellate ruling reversing the injunction.

Executed on May 1, 2013.



Janet Woodcock, M.D.